

REMARKS/ARGUMENTS

By this Amendment, claims 62-86 are added. Claims 3, 5-14, and 48-86 are pending.

Cancellation of and/or amendment to the claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The cancellation and/or amendments to the claims are being made solely to expedite prosecution of the instant application.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Citations to the Specification are directed to U.S. Patent Application Publication No. 2005/0014254 (Kruse). Support for the new claims can be found throughout the Specification as filed, and specifically, limitation for the limitation wherein the "adult stem cells which are capable of differentiating into cells of all three germ cell layers", can be found in ¶[0004] and ¶[0020]. No new matter has been added by this amendment.

The Examiner's courtesy in granting an interview to Applicants' representative on April 30, 2009 is gratefully acknowledged. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

Claim Objections

Claims 14, 48-50 stand objected to as being directed to non-elected species, it is requested that this objection be held in abeyance, since upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Rejection under 35 USC 112, first paragraph

Claims 3, 5-14, 48-61 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed.

The Examiner argues that the declaration by Dr. Kruse is not persuasive because Dr. Kruse indicates that pluripotent stem cells were obtained from salivary gland from goat (Dr. Kruse's declaration, October 31, 2008), point 8.

However, the third Declaration of Dr. Kruse under 37 CFR 1.132 submitted 10/31/2008 contained a typographical error in ¶7. In the third Declaration of Dr. Kruse, it was mistakenly set forth that the data were from salivary glands. This was a typographical error, the data is from pancreatic tissue. Applicant regrets the error.

Accordingly, submitted herewith is a Fourth Declaration of Dr. Kruse under 37 CFR 1.132, in which Dr. Kruse sets forth experimental data which includes evidence that pluripotent stem cells can be isolated from pancreatic tissue of goats, which is the third species exemplified. The characterization of the cells has been implemented and presented similar to the experiments involving cells from salivary glands submitted previously in the prosecution of this application. The differentiated cells stained positive for several cell markers having specificity for different cells of all 3 germ layers. The differentiated cells stained positive for the ectodermal cell markers GFAP and neurofilaments (see Figure 1A and 1B). The differentiated cells stained positive for the mesodermal markers collagen-II and α -smooth muscle actin (see Figure 2A and 2B). The differentiated cells stained positive for the endodermal marker cytokeratin 18 and amylase (see Figure 3A and 3B)(see the Fourth Declaration of Dr. Kruse at ¶8).

With respect to the confirmation of a normal karyotype, Dr. Kruse submits the results obtained by an independent cytogenetic laboratory located in Kaiserslautern, Germany. The findings of the independent cytogenetic laboratory are set forth in the summarizing opinion (see fourth Declaration of Dr. Kruse, ¶9, and Appendix A, "Beurteilung") with respect to the specimen (translated from the German):

Numerically and structural inconspicuous female karyotype, the satellite extension at one chromosome 22 is a normal variation without pathologic relevance.

Therefore, according to the evidence presented in the Fourth Declaration of Dr. Kruse the pluripotent stem cells isolated maintain a normal karyotype.

The Examiner further argues that nestin is not an ES cell marker. Per NIH guidelines, ES cells express Oct-4 (Office Action, April 29, 2008, page 3), and nothing in the specification provides guidance that this protein was expressed

However, Applicant points out that as set forth in the response submitted 10/29/2008, the Kajahn reference was cited which demonstrates that the marker nestin as an indicator of pluripotency has been demonstrated for pancreatic stem cells and skin-derived cells in Figs. 1 and 2 of Kajahn et al.

In addition, Wiese et al. (Cell Mol Life Sci. 2004 Oct; 61(19-20):abstract, cited on the IDS submitted herewith), teaches that nestin is abundant in ES-derived progenitor cells that have

the potential to develop into neuroectodermal, endodermal and mesodermal lineages, and that this strongly suggests that nestin actually is a pluripotent stem cell marker. Moreover, the Fourth Declaration of Dr. Kruse (see ¶8), as well as the specification as originally filed provide clear evidence for pluripotent stem cells from different exocrine tissues and different species by demonstrating that the differentiated cells obtained therefrom stain positively for several cell markers having specificity for different cells of all three germ layers (mesoderm, endoderm and ectoderm). The terms "pluripotency" or "pluripotent stem cells" as used in the present application is defined as equivalent to the "capability to differentiate into cells of all 3 germ layers". Thus, the direct evidence based on the actual presence of differentiated cells of all three germ layers is evidence for pluripotent stem cells.

Here, the Specification presents examples of pluripotent stem cells isolated from pancreas of human and rat, and that these cells have been shown to differentiate into nerve, glia, cartilage, exocrine and endocrine cells. Evidence has been submitted in the form of 1.132 Declarations showing isolation of stem cells from goat, and well as other mammals, and that the cells maintain a normal karyotype. The Specification teaches that the pancreatic stem cells can differentiate into nerve cells, glial cells, muscle cells, cartilage, exocrine glandular cells, endocrine glandular cells and epidermal cells.

Accordingly, reconsideration and withdrawal of the rejection of claims 3, 5-14, and 48-61 under 35 U.S.C. 112, first paragraph is respectfully requested.

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Amendment Dated 6/26/2009
Reply to Office Action of 01/29/2009

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

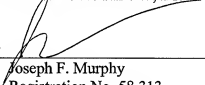
Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

June 26, 2009

Please charge or credit our
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